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ZymoGenetics, Inc.
1201 Eastlake Avenue East
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EXAMINER

SKELDING, ZACHARY S

ART UNIT	PAPER NUMBER
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1644

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/807,997

Applicant(s)

XU ET AL.

Examiner

Zachary Skelding

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-28 and 35-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 15-28 and 35-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-14 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's Amendment and Election, filed September 20, 2006, has been entered.
Claims 1-39 are pending.
2. Applicant has elected Group II, drawn to **anti-IL-20 antibodies and the species "a polypeptide consisting of amino acid residues 42-102 of SEQ ID NO:8"**. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Therefore, the restriction requirement is maintained and made **FINAL**.

3. ***Claims 6-14 and 29-34 are under consideration as they read on anti-IL-20 antibody and the species "a polypeptide consisting of amino acid residues 42-102 of SEQ ID NO:8"***.

Accordingly, claims 1-5, 15-28 and 35-39 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being directed to a non-elected invention.

4. Claims 6-14 appear to be supported under 35 U.S.C. § 112, 1st paragraph by the earlier filed applications listed in applicant's claim to the benefit of priority.

However, claims 29-34 do **not** appear to be supported under 35 U.S.C. § 112, 1st paragraph by the earlier filed applications listed in applicant's claim to the benefit of priority.

If applicant disagrees, applicant should present a detailed analysis as to why claims 29-34 have clear support in an/the earlier filed application(s).

Accordingly, the effective filing date of claims 6-14 is March 24, 2003.

Moreover, the effective filing date of claims 29-34 is the same as the filing date of the instant application, March 24, 2004.

5. Applicant's information disclosure statement, filed August 5, 2005, has been considered.
6. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.
7. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected. For example, "TaqMan" and "AmpErase" are registered, active trademarks according to the publicly available USPTO Trademark Electronic Search System; however, these terms are not accompanied by the generic terminology, e.g., TM or ®, as they occur on page 169, 1st paragraph of the instant specification.

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Each letter of trademarked terms should be capitalized wherever it appears and each trademarked term should be accompanied by the generic terminology, e.g., TM or ®. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

8. **Claims 7-9, 11, 13, 14, 30, 32 and 34 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Failure to limit the subject matter of claim from which they depend: claims 7-9 and 30

Claims 7-9 are indefinite in that they are drawn to "the antibody of claim 2..." however **claim 2 is drawn to a method of making an antibody**, not an antibody, *per se*.

Claim 30 is objected to because it is drawn to "the method of claim 29..." however **claim 29 is drawn to an antibody**, not a method.

Nevertheless, in the interest of compact prosecution, claims 7 and 8 will be read as if they depended on claim 6 and claim 30 will be read as if the preamble recited, "The antibody of claim 29..."

B. immunoconjugate: claims 8, 9, 13, 14, 32 and 34

Claims 8, 9, 13, 14, 32 and 34 are indefinite in that they are drawn to "an antibody", wherein the antibody further comprises "a radionuclide", "fluorescent marker", "chemiluminescent marker", "magnetic particle", "drug", "toxin" or "PEGylation"; however, according to the instant specification, the invention encompasses "immunoconjugates" which are the conjugate of an "antibody component" with a therapeutic agent or a detectable label, wherein an "antibody component" includes both an entire antibody and an antibody fragment. Moreover, the instant specification discloses, "[g]eneral methods for producing *conjugates comprising a polypeptide and water-soluble polymer moieties* are known in the art," and describes PEG as one such water-soluble polymer moiety (see instant specification, page 15, 3rd-5th paragraphs and page 59, 1st paragraph to page 62, 2nd paragraph). Thus, according to the instant specification, the molecules of claims 8, 9, 13, 14, 32 and 34 are "immunoconjugates", however they are being claimed as "antibodies"

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Applicant is invited to amend the instant claims to create an independent claim that recites “an antibody conjugate” in the preamble, and then recites the elements of the conjugate in the claim body.

C. Self-dependent: Claim 11

Claims 11 is indefinite in that it depends from itself.

Furthermore, although claim 11 would likely be subject to additional 35 U.S.C. § 112, 1st paragraph and prior art rejections, *claim 11 will not be further treated on its merits in the instant Office Action* because it is not clear which claim applicant would like claim 11 to depend from since anti-IL-20 antibodies, to which the instant claims are directed, would not be expected reduce the pro-inflammatory activity of IL-22 since human IL-20 and IL-22 have no apparent homology at the primary amino acid sequence level, and the instant specification does not appear to indicate that IL-20 and IL-22 interact with one another.

D. Antibody that reduces the “activity” of IL-20: Claims 29 and 30

Claims 29 and 30 are indefinite in that they recite the “the antibody reduces or neutralizes *the activity* of human IL-20”; however the instant specification does not appear to define what “*the activity* of human IL-20” encompasses, e.g., does it include IL-20 solubility, or IL-20 in vivo half-life, or IL-20 interaction with its receptor, but not IL-20 ligand-receptor signaling.

Applicant is invited to amend the instant claims to more clearly set forth their metes and bounds, for example by reciting that “the antibody neutralizes the interaction of IL-20 with IL-20RA in an in vitro cell based neutralization assay” as supported by the instant specification at page 114, 1st paragraph.

E. Applicant is reminded that any amendment to the claims or specification must be supported under 35 U.S.C. § 112, 1st paragraph by the instant specification.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. **Claims 29-34 are rejected under 35 U.S.C. 112, first paragraph**, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The instant claims are rejected under 35 U.S.C. 112, first paragraph, because the instant specification lacks sufficient enabling description for one of ordinary skill in the art to make an antibody that binds the elected species, “a polypeptide consisting of amino acid residues 42 (Ile) to 102 (Asp) of SEQ ID NO: 8”, and has the ability to “*reduce or neutralize the activity/pro-inflammatory activity of human IL20*”, as recited in claim 29 and dependents thereof.

The instant specification provides one working example of an anti-IL-20 antibody, monoclonal clone #262.7.1.3.2.4, but it does not disclose the binding specificity of this antibody, i.e., which particular epitope(s) of IL-20 it binds to, or if this antibody neutralizes IL-20 activity in vitro or in vivo.

The instant specification also asserts that, “antigenic epitope-bearing peptides and polypeptides of IL-20 are useful to raise antibodies...screen anti-IL-20 monoclonal antibodies that are neutralizing,” and states that one antigenic epitope of IL-20 is “a polypeptide consisting of amino acid residues 42-102 of SEQ ID NO:8” (see instant specification, paragraph bridging pages 98-99).

However, the instant specification does not provide sufficient guidance or direction for one of ordinary skill in the art to make antibodies against “a polypeptide consisting of amino acid residues 42-102 of SEQ ID NO:8” that reduce or neutralize the activity of human IL-20 (SEQ ID NO: 8).

The instant specification does not provide an example showing that an antibody generated against “a polypeptide consisting of amino acid residues 42-102 of SEQ ID NO:8” actually has the ability to “*reduce or neutralize the activity/pro-inflammatory activity of human IL20*”.

Furthermore, the instant specification does not provide sufficient direction or guidance as to the relationship between the *structure of the elected epitope* and the *function of IL-20*.

As is well appreciated by the skilled artisan, neutralizing anti-cytokine antibodies generally function by binding the same amino acids that the cytokine utilizes to bind its receptor. For example, neutralizing anti-IL10 antibodies have been shown to bind to the amino acid on the surface of IL-10 that are involved in binding the IL-10 receptor (see Reineke et al., Protein Sci. 1998 Apr;7(4):951-60, entire document, in particular Results pages 952-954 and Figure 5). However, as can be seen from figure 5 of Reineke, large portions of the solvent-exposed surface of IL-10 do not interact with the IL-10 receptor, and antibodies that bind these regions of IL-10 not would not be expected, *a priori*, to neutralize IL-10 interaction with IL-10R.

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It is possible that antibodies that bind the regions of IL-10 not involved in IL-10 receptor interaction could inhibit ligand-receptor interaction sterically, rather than by directly occluding ligand-receptor interaction. However, without sufficient direction or guidance concerning the structure of a cytokine and its receptor, and the amino acid residues required for receptor-ligand interaction, one of ordinary skill in the art would not know which epitopes are capable of generating such antibodies.

It is noted that the instant specification discloses IL-20 is a homolog of IL-10. However, the instant specification does not disclose the relationship between the *structure of the elected epitope* and the *function of IL-20*, i.e., does this particular IL-20 epitope encompass part of the IL20 to IL20 receptor interaction domain?

Absent objective evidence that amino acid residues 42-102 of SEQ ID NO:8 are actually involved in IL-20 to IL-20 receptor interaction, the skilled artisan would require undue trials and errors to make an antibody that *reduces or neutralizes the activity/pro-inflammatory activity of human IL20* because the binding of an antibody to a protein does not necessarily disrupt the protein's biological function.

Accordingly, undue experimentation would be required to produce the claimed invention commensurate with the scope of the claims from the written disclosure alone. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Applicant is invited to provide objective evidence that the elected epitope, as well as any of the non-elected epitopes, do indeed generate antibodies that neutralize the interaction of IL-20 with IL-20RA.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 7, 10, 12, 29-31 and 33 are rejected under 35 U.S.C. § 102(b) as anticipated by Conklin et al. (WO 99/27103, citation A15 on applicant's IDS of August 5, 2005), as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan et al. (J. Histochem. Cytochem. 1995; 43:881-886) (see entire documents).

Conklin teaches antibodies that bind to a polypeptide comprising a sequence of amino acid residues shown in SEQ ID NOs: 8 (see, in particular, page 40, 2nd paragraph).

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Conklin further teaches monoclonal antibodies that bind various epitopes of human IL-20, for example epitope-bearing polypeptides of any length up to and including the entire polypeptide, including, but not limited to, SEQ ID NOs: 25-32 of Conklin (see, in particular page 5, 2nd paragraph), many of which substantially overlap with the elected species, such as SEQ ID NO: 28 of Conklin (residues 35-105 of SEQ ID NO: 2) and SEQ ID NO: 29 of Conklin (residues 35-126 of SEQ ID NO: 2).

Conklin also teaches that SEQ ID NO: 8 may be involved in "cytokine production of other inflammatory mediators, such as eosinophils...", and that antagonists of SEQ ID NO: 8, ***including antibody antagonists***, can reduce/neutralize IL-20 activity/pro-inflammatory activity, for example, by antagonizing "ligand binding and signal transduction in vitro and in vivo." (see, in particular, page 41, 1st paragraph and page 43, 1st paragraph).

Lastly, Conklin teaches polyclonal antibodies that bind SEQ ID NO: 8, antibody fragments and genetically engineered antibodies (see, in particular page 40, 2nd paragraph to page 41, 1st paragraph).

Moreover, as evidenced by Bost, antibodies can be specific for a given epitope and cross-reactive with multiple antigens. For example, Bost teaches antibodies which cross-react with IL-2 and HIV envelope protein, and establish that the binding to each protein is due to the presence of a homologous sequence in each protein of six amino acids, four of which are identical (see entire document, in particular the Abstract and Discussion, pages 577 and 583-585). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (see, in particular Results, pages 579-583).

As further evidenced by Bendayan et al., a monoclonal antibody can be highly specific for a given epitope and cross-reactive with antigens from different species or even distinct proteins not related to the original antigen (See entire document, in particular Discussion, pages 886-887).

Given the antibodies of Conklin which bind residues 35-105 and 35-126 of SEQ ID NO: 8, sequences which encompass the elected epitope - residues 42-102 of SEQ ID NO: 8 - and given that antibodies can be both specific and cross-reactive with antigens from different species (or even distinct proteins not related to the original antigen) as evidenced by Bost and Bendayan, the antibodies of Conklin would bind residues 42-102 of SEQ ID NO: 8.

Therefore, the teachings of Conklin, as evidenced by Bost and Bendayan, anticipate the claimed invention.

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Since the Office does not have a laboratory to test the antibodies of Conklin, it is applicant's burden to show that the antibodies of Conklin do not bind residues 42-102 of SEQ ID NO: 8 and/or do not reduce or neutralize human IL-20. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **Claims 6-10, 12-14 and 29-34 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Conklin et al. (WO 99/27103, citation A15 on applicant's IDS of August 5, 2005), in view of Xu et al. (WO 2003/083062), Koumenis et al. (Int J Pharm. 2000 Mar 30;198(1):83-95), Harlow et al. (Antibodies, Cold Spring Harbor Press, pp. 319, 321-326, 340, 342-345, 350, 353 and 358 (1988)) and Reff et al. (Crit Rev Oncol Hematol. 2001 Oct;40(1):25-35)(See entire documents).

The teachings of Conklin are described in section 12 above.

The claimed invention differs from the reference teaching in the recitation of "wherein the antibody further comprises "a radionuclide, enzyme, substrate, cofactor, fluorescent marker, chemiluminescent marker, peptide tag, magnetic particle, drug, or toxin" and "wherein the antibody further comprises PEGylation" and wherein the antibody is "human" or "humanized".

Xu teaches an IL-20 related cytokine known as "IL-TIF". Xu also teaches that IL-20 and IL-TIF share a receptor subunit, that IL-20 and IL-TIF activity are implicated in the pathogenesis of psoriasis, and that mice transgenic for IL-20 and IL-TIF have similar phenotypes (see, in particular, page 65, 1st paragraph to page 67, 1st paragraph). Finally, Xu teaches human and humanized anti-IL-TIF antibodies can be labeled with a radionuclide, enzyme, substrate, cofactor, fluorescent marker, chemiluminescent marker, peptide tag, magnetic particle, drug, or toxin or pegylated (see entire document, in particular, paragraph bridging pages 5-6 to paragraph bridging page 10, 3rd paragraph; page 53, 1st paragraph; page 55, 1st paragraph to page 57, 1st paragraph; page 87, 1st paragraph to page 89, 2nd paragraph, and claims 3 and 5, for example).

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Harlow teaches that antibodies can be labeled with a radionuclide, enzyme, substrate, cofactor, fluorescent marker, chemiluminescent marker, or a peptide tag. It is noted that the phrase "peptide tag" as recited in the instant claims, given its broadest reasonable interpretation consistent with the instant specification at page 56, 2nd paragraph, reads on any peptide that can be fused to an antibody and used to purify said antibody, for example β -galactosidase or streptavidin antibody conjugates as taught by Harlow, which, as is well known to one of ordinary skill in the art, can be purified via anti- β -galactosidase antibody or biotin column chromatography. Harlow also teaches that labeled antibodies have many uses such as cell sorting, immunohistology and immunoassays (see entire document).

Reff teaches linking toxins and drugs to antibodies (see entire document, in particular page 28, section 3.2-3.3). Reff further teaches human and humanized antibodies.

Koumenis teaches the PEGylation of an anti-interleukin antibody, anti-IL-8, to increase serum half-life and to reduce immunogenicity (see entire document, in particular Introduction, page 84).

Given the teaching of Conklin and Xu, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill in the art would have been motivated to label the anti-IL-20 antibodies of Conklin using the radionuclide, enzyme, substrate, cofactor, fluorescent marker, chemiluminescent marker, peptide tag or magnetic particle labels recited by Xu because, as taught by Xu, both IL-20 and IL-TIF activity are implicated in the pathogenesis of psoriasis, and thus one of ordinary skill in the art would have been motivated to prepare an antibody to detect the expression of IL-20 in psoriatic skin by labeling the antibody according to Conklin with the labels of Xu.

Moreover, it would have been further obvious to one of ordinary skill in the art, and one of ordinary skill in the art would have further been motivated to label the anti-IL-20 antibodies of Conklin using the labels taught by Harlow in light of the teachings of Conklin that IL-20 may be involved in "cytokine production of other inflammatory mediators, such as eosinophils...", and as is well known to one of ordinary skill in the art, labeled antibodies to pro-inflammatory molecules have a variety of additional art recognized experimental uses including, as taught by Harlow et al., cell sorting, immunohistology and immunoassays.

Moreover, as taught by Xu, Koumenis and Reff, one of ordinary skill in the art would have been motivated to prepare human, humanized or pegylated versions of the anti-IL-20 antibodies of Conklin because such antibodies have lower immunogenicity and a longer serum half-life than alternative molecules like mouse/human chimeric antibodies. As is well known to one of ordinary skill in the art, antibodies are generally administered by injection in a physicians office, and thus patients and their physicians greatly desire antibodies with a long serum half-life and low immunogenicity.

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Furthermore, given the teaching of Conklin that SEQ ID NO: 8 may be involved in “cytokine production of other inflammatory mediators, such as eosinophils...”, and that antagonists of SEQ ID NO: 8, **including antibody antagonists**, can reduce/neutralize IL-20 activity/pro-inflammatory activity, for example, by antagonizing “ligand binding and signal transduction in vitro and in vivo,” one of ordinary skill in the art would have been motivated to prepare an anti-IL-20 antibody toxin or drug conjugate as taught by Xu or Reff to deliver a toxin or drug to a cell that expresses the IL-20 receptor thereby killing the inflammatory cells and treating inflammation, for example the inflammation associated with psoriasis.

Given the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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15. **Claims 6-10, 12-14 and 29-34 are provisionally rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8, 10, 12, 14, 17-23, 25 and 26 of copending and apparently commonly assigned **USSN 10/789,968** in view of Xu et al. (WO 2003/083062), Koumenis et al. (Int J Pharm. 2000 Mar 30;198(1):83-95), Harlow et al. (Antibodies, Cold Spring Harbor Press, pp. 319, 321-326, 340, 342-345, 350, 353 and 358 (1988)) and Reff et al. (Crit Rev Oncol Hematol. 2001 Oct;40(1):25-35)(See entire documents).

The claims of **USSN 10/789,968** recite an antibodies that bind SEQ ID NO: 2 and various SEQ ID NO: 2 peptides, wherein SEQ ID NO: 2 is the same as SEQ ID NO: 8 of the instant application.

The claims currently under consideration which are not anticipated by **USSN 10/789,968** differ from the claims of **USSN 10/789,968** in the recitation of “wherein the antibody reduces or neutralizes the pro-inflammatory activity of IL-20” and wherein the antibody further comprises certain labels or pegylation.

However, for the reasons stated in section 14 above, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill in the art would have been motivated and had a reasonable expectation of success of combining the teachings of Xu et al., Koumenis et al., Harlow et al. and Reff et al. to arrive at all of the instant claims.

This is a provisional obviousness-type double patenting rejection.

16. **Claims 6-9 are rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of apparently commonly assigned US Patent No. **7,119,175** in view of Xu et al. (WO 2003/083062), Koumenis et al. (Int J Pharm. 2000 Mar 30;198(1):83-95), Harlow et al. (Antibodies, Cold Spring Harbor Press, pp. 319, 321-326, 340, 342-345, 350, 353 and 358 (1988)) and Reff et al. (Crit Rev Oncol Hematol. 2001 Oct;40(1):25-35)(See entire documents).

Claim 1 of copending and apparently commonly assigned US Patent No. **7,119,175** recites an antibody that binds SEQ ID NO: 2, wherein SEQ ID NO: 2 is the same as SEQ ID NO: 8 of the instant application.

The term “antibody” recited in claim 1 of US Patent No. **7,119,175**, given its broadest reasonable interpretation consistent with the specification of US Patent No. **7,119,175** reads on polyclonal antibodies, monoclonal antibodies and antibody fragments.

The claims currently under consideration which are not anticipated by US Patent No. **7,119,175** differ from the claims of US Patent No. **7,119,175** in the recitation of wherein the antibody further comprises certain labels or pegylation.

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However, for the reasons stated in section 14 above, it would have been obvious to one of ordinary skill in the art, and one of ordinary skill in the art would have been motivated and had a reasonable expectation of success of combining the teachings of Xu et al., Koumenis et al., Harlow et al. and Reff et al. to arrive at all of the instant claims.

This is a provisional obviousness-type double patenting rejection.

17. Claims 6-10, 12-14 and 29-34 are directed to an invention not patentably distinct from the particular claim of apparently commonly assigned **USSN 10/789,968** OR US Patent No. **7,119,175**. Specifically, see sections 16 and 17 above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). The commonly assigned claims, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned cases qualify as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

18. Claims 6-10, 12-14 and 29-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 10-15, 22-24 and 39-53 of copending **USSN 10/994116**.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of **USSN 10/994116** recite monoclonal antibodies that bind SEQ ID NO: 2 (IL-20), which is identical to SEQ ID NO: 8 of the instant application, wherein said antibodies are labeled or pegylated and neutralize the pro-inflammatory activity of IL-20. The claims of **USSN 10/994116** also recite antibody that binds to particular amino acid sequences of SEQ ID NO: 2 which are the same as the amino acid sequences recited in claims 29-34 of the instant application.

This is a provisional obviousness-type double patenting rejection.

19. No claim is allowed.

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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
November 25, 2006

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